



WEEK ENDING AUGUST 22, 2014

OPP Weekly Activity Report

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PESTICIDE RE-EVALUATION DIVISION

Spiromesifen First Registration Review Team Meeting Held. On August 14, 2014, the team members from BEAD, EFED, HED, RD, and PRD met to discuss and coordinate the registration review of Spiromesifen. Spiromesifen was registered on May 3, 2005 as an insecticide mainly used as a miticide on a variety of crops (seed crops, low-bush, and greenhouse), ornamental flowering plants, and fruit trees. There are no residential uses. Spiromesifen belongs to a new class of pesticides, the keto-enols. The keto-enols are derivatives of tetrone acid (spirocyclic tetrone acids) and are reported to act through inhibition of lipid biosynthesis. This active ingredient works on all developmental stages of mites and used to control a broad spectrum of mite pests and whiteflies and is effective against whitefly nymphs and pupal stages. Spiromesifen is applied aerially, by ground sprayers, chemigation equipment, and tank mixes. No RED was issued for this chemical. The registration review docket initiating a 60-day public comment period on the spiromesifen is scheduled to open March 2015, and will include a Preliminary Work Plan and supporting documents. The Final Work Plan is scheduled for completion August 2015. (Julia Stokes, (703) 347-8966)

Diazinon Meeting with ADAMA and Drexel to Discuss Registration Review. On August 18, 2014, members of OPP's diazinon team met with the diazinon technical registrants, ADAMA (formerly MANA) and Drexel, to discuss outstanding questions about certain missing use parameters on diazinon labels and the submission of amended labels for diazinon. USDA and the Fish and Wildlife Service were also in attendance. EPA will request amended diazinon labels via an Agency-initiated action in fall 2014 and both technical registrants have agreed to submit amended diazinon labels to include missing use parameters. Diazinon is a restricted use organophosphate pesticide currently registered for use on various fruits, vegetables, nuts, ornamentals grown outdoors in nurseries, and cattle ear tags. The registration review risk assessment for diazinon is currently scheduled to be published in spring 2015. Diazinon is a pilot chemical for implementing the interim approaches for endangered species assessment. (Khue Nguyen, (703) 347-0248)

4-chlorophenoxyacetic acid (4-CPA) Combined Workplan & Proposed Interim Registration Review Decision Completed. The combined Workplan and Proposed Interim Decision Document for 4-chlorophenoxyacetic acid (4-CPA) was signed on August 15, 2014. 4-CPA is a plant growth regulator registered for use exclusively as a soaking agent for mung bean sprouts in greenhouse operations to prevent root formation. In the process of developing the preliminary work plan, the Agency determined that it could rely on available information to develop draft human health and environmental fate and effects risk assessments in support of registration review, and that additional data was not needed to make a

proposed interim decision on 4-CPA. Therefore, EPA is issuing a combined work plan, summary document, and proposed interim decision, which concludes that: (1) no additional data are required at this time; and (2) no changes to the affected registrations or their labeling are needed at this time. EPA has not identified any risks of concern to human health. Currently registered uses of 4-CPA are not expected to result in adverse effects to listed or non-listed species, or critical habitats. As such, EPA anticipates making a “no effect” determination under the Endangered Species Act for all listed species and no adverse modification of designated critical habitats for such species is expected for all currently registered uses of 4-CPA. In this Proposed Interim Registration Review Decision, EPA is not making human health or environmental safety findings associated with the Endocrine Disrupter Screening Program (EDSP) for 4-CPA. EPA expects to publish the combined workplan & proposed interim decision in September, 2014. Before completing this Registration Review, the Agency will make an EDSP FFDCA section 408(p) determination. (Miguel Zavala, 703-347-0504)

Ancymidol Interim Registration Review Decision Completed. The Pesticide Re-evaluation Division completed the Interim Registration Review Decision for the plant growth regulator ancymidol on August 15, 2014. Ancymidol is used only in commercial nurseries and greenhouses. Fewer than 20 pounds of ancymidol are produced and used each year, and environmental exposure is expected to be negligible. Therefore, EPA has made a “no effect” determination for ancymidol under the Endangered Species Act and determined that consultation with the Services is not required. At this time, EPA is not making human health or environmental safety findings associated with the Endocrine Disrupter Screening Program (EDSP). The ancymidol proposed interim decision was published on June 4, 2014 and EPA took public comments for 60 days, until August 4, 2014. EPA received only one comment on the interim registration review decision, from the Center for Biological Diversity (CBD), one of the key public interest groups in the endangered species arena. CBD concurs with EPA’s interim proposed registration review decision. EPA expects to publish the interim registration review decision for ancymidol in September, 2014. Before completing this Registration Review, the Agency will make an EDSP FFDCA section 408(p) determination. (Christina Scheltema, 703-308-2201)

FIELD & EXTERNAL AFFAIRS DIVISION

FEAD Presents to the National Ag Safety School on the Proposed WPS Changes.

On Wednesday, August 20, the Certification and Worker Protection Branch briefed the 150 participants attending the National Agronomic, Environmental, Health and Safety School (also known as the National Ag Safety School) on the proposed Worker Protection Standard changes. Participants at the Ag Safety School are usually the environmental, health and safety managers at agricultural

retailers and distributors. Nancy Fitz presented information on the full range of WPS proposed revisions including pesticide safety training, hazard communications, notification, personal protective equipment, decontamination and emergency assistance. She also covered changes to definitions and information on the costs and benefits of the rule. CWPB received questions about the proposed training, notification, minimum age and PPE requirements. (Nancy Fitz, 305-7385)

BIOLOGICAL & ECONOMIC ANALYSIS DIVISION

BEAD Coordinates Methyl Bromide Conference Call with Stakeholders. On August 19, 2014, BEAD arranged a conference call with the Country Ham Critical Use Exemption Stakeholders. In addition to BEAD, EPA's Office of Air and Radiation, USDA, and the Department of State, the country ham researchers were included on the call. During the call, the applicants were informed of the results of the Montreal Protocol Open-Ended Working Group meeting held last month. At that meeting, the country ham stakeholders were informed that the interim recommendation by the Methyl Bromide Technical Options Committee was for 3,240 kg of methyl bromide for country ham, the full amount nominated by the United States. The discussion included topics to help applicants prepare their critical use applications for use of methyl bromide in 2017, including emissions control and stocks. (Colwell Cook, 308-8146; Michelle Ranville, 347-8666; Bill Chism, 308-8136)

Mineral Oil for Induced Resistance and Health Benefits in Grasses. A product known as "Civitas" is registered for use on grass to control fungal pests. This product contains mineral oil. The registrant (Petro-Canada, Ontario, Canada) requested Biopesticide and Pollution Prevention Division (BPPD) to add additional pesticide claims (such as induction of induced systemic resistance by this product to combat pests) and plant health benefits (such as improved turf quality, improved delay of onset of dormancy, better tolerance to environmental stresses) to the label. On August 21, 2014, representatives from different divisions (BPPB, BEAD, EFED, and RD) and the registrant had a conference call to discuss these claims and data requirement for validating these claims. The team clearly provided instruction and data requirement to the registrant if the registrant want to make claimed changes in the current label. Additional meetings with the registrant may be held in near future (approximately 90- 120 days). (Tara Chandgoyal, 308-8257)



BEAD Excellence in Government (EIG) Fellow Completes Fellowship Program for the Year 2013-2014. As part of the year-long leadership development program, BEAD EIG Fellow Jafrul Hasan has been participating the EIG Fellows Program for the year 2013-2014. The EIG Fellows are mid-level federal leaders/managers learning to solve national challenges by driving innovation, inspiring employees and delivering results. Graduation from the program requires mastery of the topics covered at each of the program's seven sessions. The session themes are

based on the Executive Core Qualifications. Fellows learn through a variety of methods including readings, classroom discussions, one-on-one coaching, 360 assessments, guest speakers, simulations and case studies. BEAD EIG Fellow graduated from the program on Aug 14, 2014 along with 210 other Fellows representing a total of 32 agencies. BEAD Director Yu-Ting Guilaran also attended the graduation ceremony as the Agency guest. In fulfillment of the graduation requirement, a team of 5 Fellows including BEAD EIG Fellow, partnered with a government agency (in this case the Department of Transportation (DOT) and addressed a real specific federal problem in an effort to come up with implementable solutions. To that end, a white paper was submitted and a seminar was presented by the team at DOT. The BEAD Fellow also wishes to conduct a debriefing and share the experience as a Fellow with OPP Leadership. (Jafrul Hasan, 410-305-2657)

Second Training Session Completes on PCR Method for *Bacillus anthracis* Sterne.

A partnership is underway between the Office of Emergency Management (OEM) and the Office of Pesticide Programs (OPP) to conduct the Rapid Viability Polymerase Chain Reaction (RV-PCR) method, jointly developed by the Office of Research and Development (ORD) and the Lawrence Livermore National Laboratory (LLNL). As part of the ongoing partnership, quarterly training sessions (each session consists of 2-3 days) are conducted at MLB to detect *Bacillus anthracis* Sterne strain (an avirulent strain) as a surrogate for virulent anthrax employing two sets of primers and probes (markers) specific for wild type virulent *B. anthracis* strain. The purpose of training sessions is to remain proficient in conducting RV-PCR in case of a regional or national event. The second training session was conducted successfully. Each analyst processed three wipe samples: two inoculated positives and one negative control, originally received from LLNL, and obtained the desired results (known positive samples exhibited positive results while negative control remained negative). In response to MLB's previous recommendation, it was observed that LLNL has improved the sensitivity of one set of primers/probes used in the training session. (Jafrul Hasan, 410-305-2657)

INFORMATION TECHNOLOGY & RESOURCES MANAGEMENT DIVISION

 OPP FOIA Request Status Report for Aug 11- 15, 2014 							
Requests Received		Requests Closed			Requests Open		
FY14	This Week	FY14	FYTD	This Week	FY14	Prior Years	Total
465	10	289	323	4	176	222	398

(Ana Espinoza, 703-347-0102)

Rodenticide FOIA Requests - The last five of the eighteen FOIA requests submitted by the Law Office of Arnold & Porter, counsel for Reckitt Benckiser were closed due to their withdrawal by the requester. Over 25,000 records were collected from IO, RD, HED, EFED, PRD, BEAD and ITRMD. Prior to settlement with the Agency and the registrant, over 4,100 records that consisted of emails, science reviews/DERs, incident reports, regulatory records, meeting documents, EIS reports, non-confidential data production and documents cited in the OPP Public Docket were released after undergoing the FOIA CBI review process. The processing of these requests required over 700 FTE hours. (Sharon McBride, 703-305-5232)

Endangered Species Case – NCAP v. EPA Web Page Available. The ITRMD Web Team worked with FEAD to publish a new web page on the Endangered Species Case – Northwest Center for Alternatives to Pesticides (NCAP) v. EPA. This action is directed by a stipulated injunction (agreed to by the parties) that settles litigation brought against EPA by the NCAP and others in U.S. District Court in Washington State. For background information and links to FR Notices and Court Orders, please visit <http://www.epa.gov/oppfead1/endanger/litstatus/ncap-v-epa.html> (Christine Tran, 703-305-1577)

Public Participation Actions Added to Chemical Search. The OPP ITRMD Web Team worked with BPPD to post information about the proposed registration decision for the new active ingredient [Sarmentine](#). Risk assessments and proposed product labels are available for comment and the comment period closes on August 25, 2014. For information on these or other chemicals, please visit the [OPP's Chemical Search Database](#). (Miriam Organic, 703-605-0583)

Environmental Chemistry Methods (ECM) Index Updated. The ITRMD Web Team worked with EFED to update the ECM Index tables with the Environmental Chemistry Method, Independent Laboratory Validation (ILV) and EPA Review for several chemicals. The chemicals that were updated are pyrozasulfone, zoxamide, trifloxystrobin, vernolate, diflubenzuron, fluxapyroxad, penflufen, cyflufenamid, sedaxane. For more information, please visit <http://www.epa.gov/pesticides/methods/ecm-2.html>. (ITRMD Web Team, 703-605-0564)

Minor Uses Website Updated. The ITRMD Web Team worked with RD to publish a new Exclusive Use Petition for the chemical [tetraconazole](#) on the Minor Uses website. Also included in this update was the [revised Q&A for Exclusive Use Data Protection for Minor Use Registrations](#). Additional information can be found on the Agency's [Minor Uses and Grower Resources](#) website. (Christine Tran, 703-305-1577)

BIOPESTICIDES & POLLUTION PREVENTION DIVISION

Public Participation Comment Period Opens for New Microbial AI. On August 12, 2014, BPPD posted a draft Biopesticides Registration Action Document and Risk Assessments in the public docket for a 15-day public comment period prior to registration of *Pseudomonas fluorescens* strain D7, a new microbial active ingredient. The new end-use pesticide product will be used for suppression of downy brome (cheatgrass), medusahead, Japanese brome, and jointed goatgrass on fields of turf and grasses grown for seed, alfalfa, wheat, barley, triticale, oat, and rangeland. Additional information is available at regulations.gov in docket # EPA-HQ-OPP-2013-0570. (Susanne Cerrelli, 703-308-8077)

BPPD Presents at IUPAC Congress on Pesticide Chemistry. From August 10 - 14, two members of BPPD attended the International Union of Pure and Applied Chemistry (IUPAC) Congress on Pesticide Chemistry in a symposium on Agricultural Biotechnology in San Francisco, CA. Shannon Borges and Alan Reynolds each gave presentations and participated in panel discussions on topics such as advances in risk assessment of RNAi-based technologies, EPA's approach to regulation of double-stranded RNA (dsRNA) based pesticides, and topics pertaining to corn rootworm (CRW) and insect resistance management (IRM). Alan also participated in a symposium on CRW resistance management. Additionally, potential issues with the use of conventional insecticides for corn rootworm control (in conjunction with Bt corn) were discussed. (Shannon Borges, 703-305-7175; Alan Reynolds, 703-605-0515).

ENVIRONMENTAL FATE & EFFECTS DIVISION

Progress on Terrestrial and Aquatic Invertebrate Toxicity Test Design and Analysis. On August 22, 2014, EFED staff visited the Wildlife International testing facility in Easton, Maryland to learn about challenges encountered in testing larval and adult honey bees in a laboratory setting. Substantial progress has been made on the development of a 10-day toxicity study with adult honey bees; however, further modifications are needed for draft protocols used to conduct chronic toxicity tests with larval bees if the studies are to include successful emergence of adult bees. The visit also provided an opportunity to discuss progress on toxicity tests involving aquatic invertebrates that live in benthic sediments and to discuss the statistical platform used by EFED to support the analysis of ecological effect tests conducted to support pesticide registrations. (Keith Sappington, 703-605-0581; Justin Housenger, 703-305-6060).

Pollinator Best Management Practice Webinars. On August 15, representatives from EFED and PRD participated in a series of webinars for the Honey Bee Health Coalition (HBHC). EPA and USDA are *ex officio* members of the HBHC Steering

Committee, and the webinars are intended to provide Coalition members with a better understanding of crop pest control best management practice (BMP) programs that currently exist, what is working, what is not working, and what gaps exist in current programs. The webinars will help form the basis of discussion for how the Coalition can promote and support BMP programs as a mechanism toward reaching its goal of working toward crop- and product-specific integrated pest management (IPM) practices and messaging to improve bee and pollinator safety. The webinars included presentations from the Pollinator Stewardship Council/American Honey Producers Association, the Canola Council, Crop Life Canada, and the North Dakota Department of Agriculture. Also, a researcher (Clinton Ottis) from the USGS presented an overview of efforts to determine which plants bees (native and managed) are likely to forage; this information can be used to identify appropriate seed mixes for developing alternative forage areas for bees. (Tom Steeger, 703-305-5444; Tom Moriarty, 703-305-5035).

EFED Presentations at ACS/IUPAC Meeting. EFED (Mah Shamim) gave two poster presentations at the combined American Chemical Society/International Union of Pure and Applied Chemistry (ACS/IUPAC) Meeting in San Francisco, CA. In the first presentation, EFED described the joint EPA, Health Canada, and California Department of Pesticide Regulation tiered risk assessment process for evaluating potential adverse effects to pollinating bees from pesticide exposure. Using measures of exposure and relevant toxicity endpoints, the assessment process can advance from a Tier 1 assessment involving laboratory-based studies with individual bees to a Tier II assessment conducted at the colony level under semi-field conditions (e.g., tunnel studies). If further refinement is needed, Tier III studies may be conducted with colonies under real-world exposure conditions in open fields. In this assessment process, the honeybee, *Apis mellifera*, is used as a surrogate for managed and native bees. A second poster presentation focused on the utility of the open field feeding study design with *Apis mellifera* to evaluate the whole-hive toxicity of imidacloprid at multiple concentrations in spiked sucrose solution. The Tier II study described in this poster provides a means of collecting dose response and potential no-observed adverse effect level (NOAEL) data at the colony level from prolonged exposure to a pesticide. (Mah Shamim, 703-305-5025).

HEALTH EFFECTS DIVISION

Presentation and Symposium on Bystander and Worker Risk at IUPAC Meeting: A presentation was made on the draft agency policies for spray drift and volatilization at the 13th IUPAC International Congress of Pesticide Chemistry last week in San Francisco CA. The presentation was followed by a discussion period. The topics which were discussed were very broad and other speakers were from Australia, India, Japan, California, Brazil and England. One issue which was discussed in a separate meeting with symposium organizers and Crop Life

International included using available tools like PHED and the AHETF data as a basis for risk assessment in countries such as India, Brazil, and Singapore. International harmonization on occupational and residential risk assessment was also discussed along with a conceptual proposal for a workshop on that topic here in Washington (Jeff Dawson, 305-7329).

HED Staff meet USDA/FSIS Staff QA Chemists on FSIS Analytical Chemistry

Methodology: OPP's Matthew Crowley, David Miller, David Hrdy, and Steve Nako met with USDA's Food Safety and Inspection Service (FSIS)'s Staff QA Chemists LT Oliver Ou and Louis Bloum for an update on current FSIS efforts to expand the scope of current FSIS analytical chemistry methods for detecting pesticides in beef, pork, and poultry. The USDA PDP program is no longer monitoring these commodities, and OPP will in the future be relying on pesticide data from FSIS for risk assessments involving meat, pork, and poultry. The efforts stem from a GAO investigation of FDA, USDA, and EPA with respect to agency interactions involving food safety and tolerances, and EPA's recently-developed priority list for analytes in these animal commodities. During the meeting, OPP provided a general overview of USDA's PDP. FSIS updated OPP on the progress of on their work to respond to the pending release of a GAO report, including, in particular, their considerable improvement over the last six months in their ability to detect what EPA has listed as "Highest Priority" and "High Priority" pesticides in meat, poultry and pork. Chemical monitoring, priorities, schedules, and future plans for data sharing on the part of FSIS were also discussed. (David Hrdy, 305-6990)

OPP Provided a Presentation to Update Activities for USDA/FSIS SAT Meeting:

OPP's David Miller and David Hrdy attended USDA's Food Safety and Inspection Service's Surveillance Advisory Team meeting. The Surveillance Advisory Team (SAT) is an interagency committee comprised of representatives from USDA (FSIS, AMS, and ARS), FDA (CVM and CFSAN), CDC, and EPA, and consists of experts in veterinary medicine, toxicology, chemistry, and public health who provide professional advice, as well as information on veterinary drug, pesticide, and environmental contaminant residues. The purpose of the SAT is to enhance communication among participating agencies that support the National Residue Program (NRP). Discussions included veterinary drugs, pesticides, and environmental contaminants that may appear in FSIS-regulated products. The SAT discussions are used to decide which compounds may represent a public health concern and warrant inclusion in the NRP scheduled sampling plans. David Hrdy presented some ongoing activities in OPP's HED including the MRLdatabase.com pesticide and veterinary drug MRL database which was received with a lot of enthusiasm; updated information on our work with JIFSAN on [updated dietary consumption and recipe data](#) for 2005-2010; work with [Crème Global](#) and industry representatives on the development the web-based CARES-NG exposure software; and our efforts at updating our DEEM/Calendex exposure software with

the most recent NHANES/WWEIA consumption data and recipes. (David Hrdy, 305-6990)

REGISTRATION DIVISION

RD Label Approval E-Stamp/E-Signature Pilot On June 16 – August 15, 2014, the Registration Division (RD) piloted a new e-process to increase efficiency and quality control in the label approval procedure. The current label approval process involves hand-stamping and signing hard copies of the label and decision letter, sending those hard copies to contractors for QA/QC review, then posting scanned copies of the documents to the Pesticide Product Label System (PPLS). The pilot workgroup included members from the Antimicrobials Division (Elizabeth Watkins); RD (Shaunta Hill, Julie Chao, Jennifer Urbanski, Jennifer Gaines, and Bewanda Alexander), and ITRMD (Mark Heflin and Andrew Cox); two RD branches participated in the pilot (Insecticide-Rodenticide Branch and Insecticide Branch). The pilot tested a new process in which labels and letters are e-stamped and e-signed, QA/QC checked within RD, then uploaded automatically to PPLS daily as fully electronic PDFs. Benefits from the piloted process include the following: **(1)** average time from label approval to PPLS posting decreased from 16 days using the current process to 3 days using the new e-process; **(2)** PDFs of the labels are almost immediately available on PPLS for electronic label comparison; **(3)** the process can be completed by label reviewers when working from home; **(4)** there is a higher level of quality control as mistakes in letters/labels are identified within RD earlier in the process; and **(5)** there is a time and resource savings for ITRMD as contractors no longer have to QC/QA labels and letters, nor scan and paginate the documents. RD plans to implement this process division-wide in September. (Jennifer Urbanski, 703/347-0156)

Section 18 Authorized for Use of Sulfoxaflor on Sorghum in Tennessee On August 18, 2014, EPA authorized a Section 18 Emergency Exemption to the Tennessee Department of Agriculture for the use of sulfoxaflor on sorghum to control sugarcane aphid. Unusually high populations of aphids are causing direct plant death from aphid feeding as well as indirect damage and harvesting issues from the aphid honeydew residue. This pest situation could be potentially disastrous for the 2014 growing season. The Section 8 authorization expires October 31, 2014. (Keri Grinstead, 703/308-8373)

Registration Actions Granted Under FIFRA Section 18 Emergency Exemptions					
State/Federal Agency	Chemical Emergency Exemption Number	Product Name EPA Reg/ File Symbol	Crop/Site	Pest	Authorization Date
Specific Exemption(s)					
Tennessee	Sulfoxaflor (14-TN-02)	Transform® WG (62719-625)	Sorghum	Sugarcane aphid	8/18/2014
Keri Grinstead, 703/308-8373					

Registration Actions Completed Under the Pesticide Registration Improvement Act (PRIA)					
Chemical	Company	Registration Number	Action Code*	Due Date	Response Date
The Fungicide Branch granted:					
Propylene oxide	Aberco, Inc.	47870-3	R350	9/2/2014	8/19/2014
Heather Garvie, 703/308-0034					
The Herbicide Branch granted:					
Pyridine	Dow AgroSciences LLC	62719-684	R300	8/25/2014	8/20/2014
Sarah Meadows, 703/347-0505					
Glufosinate	United Phosphorus, Inc.	70506-307	R333	8/20/2014	8/20/2014
Grant Rowland, 703/347-0254					
The Insecticide Branch granted:					
Canola oil	W. Neudorff GMBH KG	67702-14	R340	8/25/2014	8/20/2014
Carlyn Petrella, 703/347-0439					
The Insecticide-Rodenticide Branch granted:					
Diflubenzuron	Champion Farmaquimico, LTDA	85905-7	R333	9/2/2014	8/15/2014
Dani Daniel, 703/305-5409					
Novaluron	Control Solutions, Inc.	53883-348	R340	8/18/2014	8/18/2014
Jennifer Gaines, 703/305-5967					
PRIA Categories					
R300 – New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation or selective data citation where applicant owns all required data or submits specific authorization letter from data owner; category also includes 100% repackage of registered end-use or manufacturing-use product that requires no data submission or data matrix (3) (4) ; R333 – New product; MUP or End use product with unregistered source of active ingredient; requires science data review; new physical form; etc. Cite-all or selective data citation where applicant owns all required data (2) (3) ; R340 – Amendment requiring data review within RD (e.g., changes to precautionary label statements) (2) (3) ; and R350 – Amendment requiring data review in science divisions (e.g., changes to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement) (2) (3) .					